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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,535	10/03/2003	Janmarie Hornack	30900-CNT2	3990

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Law Office of McMahon
P.O. Box 30069
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EXAMINER	
ARIANI, KADE	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/679,535	**Applicant(s)** HORNACK ET AL.
	Examiner KADE ARIANI	**Art Unit** 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _24 November 2008_.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1,2,7,14-17 and 19_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) _19_ is/are allowed.

6)☒ Claim(s) _1,2,7 and 14-17_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on December 22, 2008, has been received and entered.

Claims 1, 2, 7, 14-17, and 19 are pending in this application.

1.131 Declaration

The supplemental declaration filed on September 10, 2007 and the declaration which was filed on January 21, 2005 and was incorporated by reference into the supplemental declaration, have been considered but are ineffective to overcome the Walsh reference, for the following reasons:

It must be noted that although the declarations of Janmarie Hornack filed on 09/10/2007 and 1/21/2005 were not identified as declarations under 1.131, however are considered to be under 1.131.

The declarations are not signed by all the inventors.

The date (next to the signature) on the supplemental declaration is September 7, 2009, a date which has not come.

The declaration filed on 01/21/2005 has no date.

The evidence submitted on 09/10/2007 and 01/21/2005 are insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Walsh et al. reference. The rule requires an averment that the invention was made in the United States.

In contrast to applicant's assertion's that the exhibits A and B have confirmed reduction to practice of the entire subject matter of the claimed subject prior to 03/10/1997, the evidence/laboratory data provided are not commensurate in scope with the claimed subject or the prior art. Exhibits differ from the claims and the prior art, in that they provide for a mixture of supplement/nutrients and there is no evidence that the exhibit were drawn to a dietary or therapeutic supplement for human consumption. Moreover, the exhibit differ in pH or ranges of pH from the claimed invention compositions and prior art. For example the claims are drawn to pH of 6 or less, and to raise the pH to a pH of from 8 to about 12.5, while the pH of agents in the exhibit are pH 7.2, 7.6, 7.17, 7.11, 7.01, and 7.35.

While Applicant has provided notebook pages as evidence of conception, diligence and reduction to practice, these pages are not clear on their face. Applicant has the burden to explain the contents of the pages as proof of acts amounting to conception, diligence and reduction to practice. Absent a clear explanation of pointing out exactly what facts are established therein and relied upon by applicant, the laboratory notebook pages provide little assistance in enabling PTO to determine applicant’s assertions of conception, diligence and reduction to practice before the prior art.

Response to Arguments

Applicant's arguments filed on 11/24/2008 have been fully considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/21437.

Claims 1, 2, and 7 are drawn to an alkaline dietary and/or therapeutic supplement composition for human consumption consisting essentially of a solid dietary supplemental agent selected from a water soluble vitamin (bioflavonoids, minerals, trace minerals, whole plant food products containing phytotnutrients, herbs and mixtures thereof), having an initial pH of 6 or less, an alkaline additives containing a mixture of calcium, magnesium and potassium electrolytes (the calcium, magnesium or potassium electrolytes are selected from the group consisting of hydroxides, chloride, di-phosphate, carbonate, gluconate, bicarbonate, phosphate, and sulfate), the amount of additive being sufficient to raise the pH of the of from about 8 to about 12.5, the pH in the range of about 8 to about 10.5, and ascorbic acid.

WO 99/21437 disclose an alkaline dietary supplement containing a mixture of calcium, magnesium, and potassium electrolytes (potassium phosphate, magnesium carbonate, calcium chloride), amino acids, and trace minerals, to be added to vitamin-botanical dietary supplements, to provide a dietary supplement in the form of tablets (Abstract, p.4 2nd paragraph and p. 6 3rd paragraph, p. 8 lines 3 and 15). WO 99/21437 disclose providing a safe additive for a dietary supplement by adding the alkaline additive to the dietary supplement to neutralize acids and to increase the pH to about 8-10, and enable the user or patient to achieve an alkaline lifestyle (p.5 2nd paragraph lines 1-3).WO 99/21437 further discloses ascorbic acid or vitamin C (p.8 line 10).

WO 99/21437 therefore, clearly anticipated the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/21437 in view of Herschler (US Patent No. 4,568,547) and further in view of Koppel et al. (US Patent No. 5,358,720).

Claims 14, 15, and 17 are drawn to an alkaline dietary and/or therapeutic supplement composition for human consumption and consisting essentially of in combination: a solid methylsulfonylmethane (MSM) supplement agent having an initial pH of 6 or less, an alkaline additive containing a mixture of calcium, magnesium, and potassium electrolytes (the calcium, magnesium or potassium electrolyte being selected from the group consisting of hydroxides, chlorides, di-phosphates, carbonates, gluconates, bicarbonates, phosphates, and sulfates), the amount of the alkaline electrolyte additive being sufficient to raise the pH of the combination from about 8 to about 12.5, the supplement agent includes a quantity of bioflavonoids, and wherein the agent includes a quantity of MSM (pH from about 8 to about 12.5)

As mentioned immediately above, WO 99/21437 teach a an alkaline dietary supplement containing a mixture of calcium, magnesium, and potassium electrolytes, (potassium phosphate, magnesium carbonate, calcium chloride), amino acids, trace minerals, to be added to vitamin-botanical dietary supplements, to provide a dietary supplement in the form of tablets (Abstract, p.4 2nd paragraph and p. 6 3rd paragraph, and p.8 lines 3 and 15). WO 99/21437 also teach providing a safe additive for a dietary supplement by adding the alkaline additive to the dietary supplement to neutralize acids and to increase the pH to about 8-10, and enable the user or patient to achieve an alkaline lifestyle (p.5 2nd paragraph lines 1-3).

WO 99/21437 does not teach methylsulfonylmethane (MSM), and wherein the supplement includes a quantity of a bioflavonoid. However, Herschler teaches MSM is useful as a tableting and granulating aid for pharmaceutical active agents, it is an adjuvant in solid pharmaceutical compositions, and that it possesses highly desirable properties and low mammalian toxicity, because, it is a natural constituent of most fresh foods and beverages, and it is compatible with all other known tableting excipients (Abstract and column 3 lines 48-60).

Moreover, at the time the invention was made bioflavonoids and their health benefits were well known in the art.

Further motivation is in Koppel et al. who teach using calcium ascorbate, a buffered form of vitamin C in dietary supplement (column 3 lines 14-15).

Therefore, a person of ordinary skill in the art at the time the invention was made, could have been motivated to art to combine the prior art teachings and to use tableting agent MSM as taught by Herschler in the composition as taught by WO 99/21437 with predictable results of providing an alkaline dietary supplement in a tablet form. A person of ordinary skill in the art at the time the invention was made could have been motivated to include a bioflavonoid as taught by Koppel et al. in the in the alkaline dietary composition as taught by WO 99/21437 with predictable results of providing an improved alkaline dietary supplement for human consumption. The motivation would be the health benefits of flavonoids.

Accordingly Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. 103(a). Ex Parte Smith, 83 USPQ.2d at 1518-19 (BPAI, 2007) (citing KSR, 127 S.Ct. at 1740, 82 USPQ2d at 1396).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/21437 in view of Schleck et al. (US Patent No. 5,902,801).

Claim 16 is drawn to an improved alkaline dietary and/or therapeutic supplement composition for human consumption and consisting essentially of, in combination with a solid glucosamine supplement agent having an initial pH of 6 or less, a alkaline additive containing a mixture of calcium, magnesium and potassium electrolytes (the calcium, magnesium or potassium electrolytes are selected from the group consisting of hydroxides, chloride, di-phosphate, carbonate, gluconate, bicarbonate, phosphate, and sulfate), the amount of additive being sufficient to raise the pH of the of from about 8 to about 12.5.

As mentioned immediately above, WO 99/21437 teach a an alkaline dietary supplement containing a mixture of calcium, magnesium, and potassium electrolytes, amino acids, trace minerals, to be added to vitamin-botanical dietary supplements, to provide a dietary supplement in the form of tablets (Abstract, p.4 2nd paragraph and p. 6 3rd paragraph). WO 99/21437 also teach providing a safe additive for a dietary supplement by adding the alkaline additive to the dietary supplement to neutralize acids and to increase the pH to about 8-10, and enable the user or patient to achieve an alkaline lifestyle (p.5 2nd paragraph lines 1-3).

WO 99/21437 does not teach a glucosamine. However, Schleck et al. teach a composition comprising glucosamine hydrochloride (acidic pH) with potassium sulfate (alkaline additive) (Abstract and column 5 Table 1. line 1). Schleck et al. also teach salts of glucosamine hydrochloride (acidic pH) and alkaline metal sulfates such as potassium are well known. Schleck et al. teach mixed salts are used (rather than glucosamine alone) because of the instability of glucosamine, and also since the amino groups will oxidize if not completely saltified (column 1 lines 30-35). Schleck et al. also teach glucosamine is a well known and widely used substance for the treatment of arthritic and arthosic complaints (column 1 lines 19-23).

Therefore, a person of ordinary skill in the art at the time the invention was made, could have been motivated to art to combine the prior art teachings and to add the alkaline additive as taught by WO 99/21437 to glucosamine supplement as taught by Schleck et al. with predictable results of providing an alkaline supplement with glucosamine. The motivation as taught by Schleck et al. would be to increase the stability of the glucosamine supplement. Accordingly Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. 103(a). Ex Parte Smith, 83 USPQ.2d at 1518-19 (BPAI, 2007) (citing KSR, 127 S.Ct. at 1740, 82 USPQ2d at 1396).

Allowable Subject Matter

Claim 19 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651